IV. 510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Fossa Medical, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Fossa chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name:	**Fossa Ureteral OPEN-8 Stent (7 Fr and 10 Fr) Or Fossa Open-8 Stent**
510(k) Sponsor:	Fossa Medical, Inc. P.O. Box 304 Milton, MA 02186
Device Generic Name:	Ureteral stent
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (78FAD), and is classified under 21 CFR 876.4620.
Predicate Devices:	Fossa Open Lumen Stent (K033368) Fossa Double Pigtail Expanding Ureteral Stent (K021140)

AUG - 6 2008

Product Description:
The Fossa Ureteral Open-8 Stent set consists of a flexible, pigtail-tipped stent with a radiopaque push catheter. The stent is offered in various diameters and working lengths. The stent has two lumens open to the outside of the stent and two external grooves.

Indications for Use:
The Fossa Ureteral OPEN-8 Stent is indicated for use as an indwelling ureteral catheter to promote drainage of urine from the kidney to the bladder and to inhibit microbial adherence on the catheter, specifically Proteus Mirabilus and Escherichia Coli.

Safety and Performance:
Product performance testing has been provided in support of this 510(k) in accordance with FDA's Guidance for the Content of Premarket Notifications for Ureteral Stents. The materials used in the construction of the Fossa stent are identical to those used in other currently marketed urinary drainage devices.

Conclusion:
Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the Fossa Ureteral OPEN-8 Stent have been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG - 6 2008

Ms. Gloria Kolb
President
Fossa Medical, Inc.
P.O. Box 304
MILTON MA 02186

Re: K072293
Trade/Device Name: OPEN-8 Stent
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: Class II
Product Code: FAD
Dated: July 21, 2008
Received: July 22, 2008

Dear Ms. Kolb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072293

Device Name: OPEN-8 Stent

Indications For Use:

The OPEN-8 Stent is indicated for use as an indwelling ureteral catheter to promote drainage of urine from the kidney to the bladder.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072293